CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
21-146

Microbiology Review(s)

Natalia

Review for Division of Cardio - Renal Drug Products, HFD-110
Office of New Drug Chemistry, Microbiology Staff, HFD-805
Microbiologists's Review No. 1

JUN 16 2000

June 13, 2000

MICROBIOLOGY REVIEWER: Carol K. Vincent

A. 1. **NDA No.:** 21-146

DRUG PRODUCT NAME: Atropine Sulfate Injection

APPLICANT:

Abbott Laboratories
D-389, Bldg.AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

DRUG PRODUCT MANUFACTURER:

Abbott Laboratories

2. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Sterile liquid for injection.

3. **METHOD(s) OF STERILIZATION:** [ ]

4. **PHARMACOLOGICAL CATEGORY AND/OR PRINCIPAL INDICATION:**
Treatment of sinus bradycardia and incomplete atrioventricular block.

5. **DRUG PRIORITY CLASSIFICATION:** 7 S

B. 1. **DOCUMENT DATE:** December 16, 1999

2. **DOCUMENT RECEIVED FOR REVIEW:** January 24, 2000

3. **COMIS USER FEE DUE DATE:** June 17, 2000

C. **REMARKS:** This NDA is one of a series of Abbott applications being submitted per MAPP 6020.2 [*Applications for Parenteral Products in Plastic Immediate Containers,* issued September 6, 1996] addressing the change from glass container to pre-filled 5- or 10- mL plastic syringe. Atropine Sulfate Injection was on the market in 1938, and was therefore "grandfathered" under the 1938 Food, Drug and Cosmetic Act. The currently marketed form is packaged in the Abboject® glass container.

D. **CONCLUSION and RECOMMENDATION:**

We recommend **approval** of NDA 21-146 from the microbiology prospective for sterilization process validation information for this drug product, Atropine Sulfate Injection. See **"E. REVIEW NOTES:"**, below.

CC:
Orig. NDA 21-146
HFD-160/Consult/CKVincent [HFD-805]
HFD-110/FreddS/Jongedyk/Morgenstern
Drafted by: CKVincent/06-06-2000
Revised by: CKVincent/06-13-2000

/S/

Carol K. Vincent
Review Microbiologist [HFD-805]

06-13-2000

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6/16/2000

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